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8 March 2000

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Neurological Surgery
1365 B Clifton Road, NE
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Phone 404/778-4694

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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Re: FDA Proposal to Regulate Allograft Tissue

Dear FDA:

I oppose the proposal to regulate allograft bone in spinal surgery. I also object to the letters on file from Drs. Brantigan and Hacker (submitted recently).

If expressing an opinion in this debate, I think it is important for any surgeon to disclose significant financial associations with products that compete with allograft bone. I personally receive no royalties for any type of interbody bone or metallic device.

Secondly, it is inappropriate for Dr. Hacker to refer a study that was under peer review at the time of his letter. It is inappropriate and against all recommendations of the editor of the Journal of Neurosurgery. Most importantly, he is quoting a retrospective review in which only 8 patients had findings pertinent to this discussion and the follow-up is only six months. Not only is this statisitically insignificant, but also meaningless in terms of long-term follow-up. This is particularly important with allograft bone which we know takes longer to heal.

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Thirdly, we have submitted to the North American Spine Society a larger study with longer follow-up (over sixty patients and one year follow-up) showing excellent fusion results using allograft bone grafts for anterior lumbar interbody and posterior lumbar interbody fusion. Just as with the Brantigan cages, we too have adopted the use of pedicle screw fixation when using allograft bone for interbody fusion. We have been very pleased with our results and hope to have our data published in a peer-reviewed journal later this year.

Sincerely,

Gerald E. Rodts, Jr., M.D.
Assistant Professor, Neurosurgery
Emory University

Cc: Robert J. Hacker, M.D.
Dr. Brantigan

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